Electronic Version
Stylesheet Version v1.1.1

Description

EDIBLE FILM COMPOSITIONS

BACKGROUND OF INVENTION

[0001] Orally consumable films have gained acceptance in the consumer marketplace, delivering benefits such as breath freshening, oral health care, pharmaceutical delivery as well as flavor enjoyment. Such films may be prepared using a variety of materials as the primary film forming ingredients. While each of these materials has its advantages, each also has disadvantages, such as cost, availability, slow dissolution, gummy mouthfeel, lack of regulatory approval, stability, off-taste and difficulties in manufacturing. The present invention provides an improved oral film, which minimizes the disadvantages of prior film compositions.

[0002] Edible film products are known in the art. These products are designed to adhere to and rapidly dissolve in the mouth of the consumer. Edible films can provide flavor and/or oral care benefits, e.g., breath freshening to the consumer. Such films typically include a film former and

flavor or other ingredients. See, for example, U.S. Patent No. 5,948,430 and U.S. Application Publication No. US2001/0022964 Al. Edible film products are typically provided to the consumer in strip form. The strips are usually sized so that they can be placed on the tongue of a consumer. In this regard, the edible film strips typically have a size of a postage stamp or slightly larger, although they may come in many different shapes and sizes. These strips preferably have a supple texture and are non-self adhering.

[0003] One type of edible film product is distributed by the Wm. Wrigley Jr. Company under the name Eclipse Flash® Strips. This edible film product is packaged in a plastic container that includes a top that can open along a hinge. A stack of strips is located in an interior of the package, one strip on top of another. The package is designed so that the consumer can open the container and remove one strip from the stack with his or her finger.

SUMMARY OF INVENTION

[0004] It has now been discovered that high quality, low cost oral films can be economically compounded using low viscosity hydrolyzed vegetable gum as a film forming component. Films made according to the present invention dis-

solve quickly with reduced gumminess and off-flavors.

[0005] Additional features and advantages of the present invention will be described herein, and apparent from the detailed description of the invention.

DETAILED DESCRIPTION

[0006] Generally, the present invention provides edible film formulations for oral mucoadhesion, and methods of using and making same. More specifically, the present invention provides edible film formulations containing low viscosity hydrolyzed vegetable gum as a film forming agent.

[0007] Edible films of the present invention employ an effective amount of a low viscosity hydrolyzed vegetable gum. Vegetable gums are polymeric carbohydrates derived from plant materials and are commonly used as additives in a variety of food products. Although less commonly used, these gums may be hydrolyzed by acids or enzymes to produce gums having lower molecular weight. Examples of such hydrolyzed vegetable gums which may be useful in the present invention include hydrolyzed guar gum, hydrolyzed locust bean gum, hydrolyzed larch gum, hydrolyzed carrageenan, hydrolyzed gum arabic, hydrolyzed sodium alginate and hydrolyzed gum tragacanth. In an embodiment, hydrolyzed vegetable gums used in the

present invention are galactomannans. In an embodiment, hydrolyzed galactomannan is enzymatically hydrolyzed guar gum which is produced by Taiyo Kagaku Co., Ltd. and marketed in the U.S. by Novartis of Minneapolis, Minn. under the trade name Benefiber®. The use of low viscosity hydrolyzed vegetable gums provide an edible film with characteristics such that the films dissolve quickly with reduced gumminess and no off-flavors.

[0008] Hydrolyzed guar gum is in a family of vegetable gums called galactomannans. These materials are made up of mannose and galactose units. The main chain consists of (1 -> 4)-linked beta-D-mannose residues and the side chains of (l -> 6)-linked alpha-D-galactose. Locust bean gum is another galactomannan. Galactomannans themselves are part of a larger group of natural gums. PCT Publication No. WO 93/15116 discloses a process for hydrolyzing guar gum, locust bean gum and karaya gum, which are characterized as "natural carbohydrate" gums. The other hydrolyzates disclosed in the PCT Publication may be useful in a manner similar to guar gum hydrolyzate.

[0009] A preferred low viscosity hydrolyzed vegetable gum used in the present invention is hydrolyzed guar gum. This is a

flavorless, colorless, fine white powder, and is a soluble dietary fiber and is unnoticeable when added to food products. Viscosity comparisons were made between a hydrolyzed guar gum, Benefiber® and sodium alginate. Test method was using a Brookfield DVII Viscometer, using Spindle #2, at 25 degrees centigrade and sample dilutions at 15% in water. The temperature was held at 25 degrees centigrade using a jacketed beaker connected to a waterbath. The rpm adjusted per sample, to target a % accuracy of the instrument close to 50%. Using this method, the viscosity of hydrolyzed guar gum at 100 rpm was 82.4 cps. The viscosity of the sodium alginate at 2.5 rpm was 32900 cps. Not wishing to be bound by theory, it is believed that the low viscosity of the hydrolyzed guar gum, when used in an edible film formulation, decreases the gummy mouthfeel experienced with edible film formulations presently on the market. Provided the method described above, and for purposes of the present invention, a low viscosity may be defined as up to about 10,000 cps. In an embodiment of the present invention, an edible film comprises a low viscosity hydrolyzed vegetable gum having viscosity up to about 10,000 cps. More preferably, an edible film comprises a low viscosity hydrolyzed vegetable

gum having viscosity up to about 5000 cps. Most preferably, an edible film comprises a low viscosity hydrolyzed vegetable gum having viscosity up to about 500 cps.

[0010] These hydrolyzed vegetable gums are film forming agents, which may be used as the only film forming agent or in combination with other film forming agents, at levels ranging from approximately 2% to about 60% by weight (dry basis) in the films. In an embodiment, these hydrolyzed vegetable gums may be employed at levels ranging from approximately 15% to about 50% by weight. In yet another embodiment, the hydrolyzed vegetable gums will be employed at levels ranging from approximately 20% to about 45% by weight.

[0011] Typically, other ingredients will be incorporated into the edible films of the present inventions. Other ingredients may include additional film forming agents, fillers, plasticizers, flavors, emulsifiers, colors, sweeteners, high-intensity sweeteners, acids etc. Further, the edible films may include a variety of other suitable ingredients, such as softeners, heating agents, cooling agents, surfactants, thickening agents, binding agents, active agents, fragrances, other like ingredients or combinations thereof.

[0012] Additional film forming agents which may be used in the

present invention include sodium alginate, carrageenan, Pullulan, modified starch (e.g. hydroxypropyl starch), hydroxypropyl methylcellulose (HPMC), pectin, hydrolyzed alginates, polysaccharides, maltodextrin, starch, gum arabic, guar gum, larch gum, locust bean gum, xanthan gum, hydrocolloids, and combinations thereof. Such film formers also modify the texture of the edible film. The selection of film formers may make the edible film more or less brittle, and also contribute to modifying the gummy properties of edible films. The total film forming agent may be present at a level of 2% to about 60%, more preferably in amounts from about 20% to about 45% of the total film forming composition.

[0013] A hydrocolloid, mentioned above, may be derived from, for example, natural seaweeds, natural seed gum, natural plant exudates, natural fiber extracts, biosynthetic gums, gelatins, biosynthetic process starch or cellulosic materials, alginates, sodium alginate, calcium alginate, carrageenans, guar gum, locust gum, larch gum, tara gum, gum arabic, ghatti gum, agar gum, xanthan gum, pectin, other like hydrocolloid source materials or combinations thereof. The hydrocolloid, in addition to being a film former, can provide thickness and decrease brittleness of the

edible films, as mentioned above. The hydrocolloid can include any suitable type, amount and number of hydrocolloids.

[0014] Any suitable food-grade bulk filler can also be added to the edible film. This can reduce any slimy texture as well as provide structure to the film, thereby making it more palatable. In addition, fillers control gumminess and dissolution rate and they help keep the films separated from each other. In an embodiment, the filler can constitute about 2% to about 30% by dry weight of the film, preferably about 5% to about 15% by dry weight. The filler can include, for example, microcrystalline cellulose; cellulose polymers, such as wood; magnesium carbonate; calcium carbonate; ground limestone; silicates, such as magnesium silicate and aluminum silicate; clay; talc; titanium dioxide; mono-calcium phosphate; di-calcium phosphate; tri-calcium phosphate; other like bulk fillers or combinations thereof.

[0015] If reduced levels of film forming agents are utilized, softeners may be used to reduce the brittleness of the resulting films. The softeners, which are also known as plasticizers or plasticizing agents, generally constitute about up to 20% by dry weight of the film, preferably about 2% to

about 10% by dry weight. The softeners can include plasticizers containing, for example, sorbitol and mixtures of sugar alcohols, xylitol, glycerin, polyethylene glycol, propylene glycol, hydrogenated starch hydrolysates, corn syrups, glycerin, triacetin, glycerol oleate, sucrose fatty acid ester, Neobee oil, medium chain triglycerides other like material or combinations thereof.

[0016] Coloring agents which may be used in the present invention may include, for example, natural food colors and dyes suitable for food, drug and cosmetic applications. The colors, typically knows as FD&C dyes and lakes, may be present in amounts from about 0.01% to about 1.5% by weight of the edible film formulation.

[0017] A variety of flavoring agents may also be added to the edible films. Any suitable amount and type of artificial and/or natural flavoring agents can be used in any sensorially acceptable fashion. For example, the flavor can constitute about 0.1% to about 20% by dry weight of the film, preferably about 5% to about 15%. The flavoring agents can include, for example, essential oils, synthetic flavors or mixtures, including but not limited to, oils delivered from plants and fruits such as citrus oils, fruit essences, peppermint oil, spearmint oil, other mint oils, clove oils, oil of

wintergreen, anise and the like, flavor oils with germ killing properties such as menthol, eucalyptol, thymol, like flavoring agents or combinations thereof.

[0018] The flavor can be enhanced and evenly distributed throughout the product by emulsification. Any suitable amount and type of natural and/or synthetic food-grade emulsifier can be used. For example, the emulsifier can include lecithin, food-grade non-ionic emulsifiers, such as fatty acids (C_{10}-C_{18}), mono-glycerides, diacyl-glycerides, ox bile extract, polyglycerol esters, polyethylene sorbitan esters, propylene glycol, sorbitan monopalmitate, sorbitan monosterate, sorbitan tristerate, enzyme modified lecithin, hyroxylated lecithins, other like emulsifiers or combinations thereof. Emulsifiers may be used in amount ranging from approximately 0.1% to about 3%. The flavors can be emulsified by any suitable emulsification process, such as mechanical processing, vigorous stirring, intense pressure fluctuations that occur in turbulent flow such as homogenization, sonication, colloid milling and the like.

[0019] The bulk sweeteners, which may be added to the film composition, include both sugar and sugarless components. Sugar sweeteners generally include saccharide

components commonly known in the art, including but not limited to, sucrose, dextrose, maltose, dextrin, dried invert sugar, fructose, levulose, galactose, corn syrup solids, and the like, alone or in combination. Sugarless sweeteners include, but are not limited to, sugar alcohols such as sorbitol, mannitol, xylitol, hydrogenated starch hydrolysates, maltitol, and the like, alone or in combination.

[0020] High-intensity artificial sweeteners can also be used, alone or in combination, with the above. High-intensity sweeteners include, but are not limited to, sucralose, aspartame, NAPM derivatives such as neotame, salts of acesulfame, altitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizinate, neohesperidine, dihydrochalcones, thaumatin, monellin, and the like, alone or in combination. In order to provide longer lasting sweetness and flavor perception, it may be desirable to encapsulate or otherwise control the release of at least a portion of the artificial sweetener.

[0021] Flavors may also be enhanced by the use of heating and cooling agents in the edible film formulations. Cooling agents enhance the flavor and perceived breath freshening of the product. Cooling agents include N-

ethyl-p-menthane-3-carboxamide (WS-3), N,2,3 -trimethyl-2-isopropyl-butanamide (WS-23), menthyl glutarate, menthyl succinate, menthol PG carbonate, menthol EG carbonate, menthyl lactate, menthone glyceryl ketal, menthol glyceryl ether, 3,3,5-trimethylcyclohexanol (Homomenthol), isopulegol and combinations thereof. Cooling agents may be used in amounts of about 0.01% to about 2% by weight of the edible film formulation.

[0022] The present invention may also optionally contain a heating agent. The heating agent, in small amounts, potentiates the effect of the cooling agent. The heating agent may also substitute for the cooling agent in the present invention if the experience of heat, tingling or itching is desired. The heating agents of the present invention are capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof. In the present invention, generally, the heating agent may be used in amounts of about 0.01% to about 3% by weight of the film formulation.

[0023] A variety of other suitable ingredients can be added to the edible film of the present invention. For example, any suitable medicament for oral cleansing, breath freshening

or the like can be added to the film formulation. The medicaments can include, for example, a pH control agent, such as urea and buffers; inorganic components for tartar or caries control, such as phosphates and fluorides; a breath freshening agent such as zinc gluconate; an anti-plaque/anti-gingivitis agent, such as cholorhexidene, CPC, and triclosan; a saliva stimulating agent including, for example, food acids such as citric, lactic, maleic, succinic, ascorbic, adipic, fumaric and tartaric acids; a pharmaceutical agent; a nutraceutical agent; a vitamin; a mineral; other like medicaments or combinations thereof. The highly dissolvable edible film can act as a medium through which a pharmaceutically active oral agent can be administered via a mucous membrane of the oral cavity.

[0024] The present invention provides methods of producing the edible film formulations. In general, the edible film formulations are prepared by forming a base solution that includes ingredients such as maltodextrins, hydrocolloids and fillers, and processing the base solution to form an edible film. Typically, the base solution is prepared by adding an initial mixture of dry ingredients to water that is stirred.

[0025] In an embodiment, the solution is stirred continuously and

heated at a temperature ranging from about 40°C to about 60°C. The solution then can be dried in any suitable manner, thereby forming the edible film.

[0026] It should be appreciated that any suitable type, number and arrangement of process procedures or steps (i.e. mixing, heating, drying, cooling, addition of ingredients), process parameters (i.e. temperature, pressure, pH, process times) or the like can be utilized.

[0027] By way of example and not limitation, examples of embodiments of edible films are provided herein.

[0028] An edible film formulation using hydrolyzed guar gum was made and compared to a control which did not contain hydrolyzed guar gum as a film former. The protocol by which the films were produced are following Table 1.

Table 1. Film formulations (dry weight)

Ingredient	Control	Example A
Water	10.00	10.00
Sodium Alginate	26.495	16.434
Maltodextrin	23.325	16.441
Peppermint	10.158	8.895
Carrageenan	8.548	0
Microcrystalline Cellulose	7.040	7.262
Glycerine 99%	6.384	6.583

Menthol	3.565	3.126
Sucralose	3.095	2.714
Hydroxylated Lecithin	1.082	0.948
Color	0.308	0.270
Benefiber® (hydrolyzed guar gum)	0	27.327
Total	100	100

[0029] Preparation of films in Table 1: Step 1 – Dry blend sodium alginate, maltodextrin, carrageenan and microcrystalline cellulose (and/or other hydrocolloids per formula in Table 1). Step 2 – Blend peppermint, menthol and hydroxylated lecithin. Step 3 – Add color to room temperature, deionized water. Step 4 – Add dry ingredients from step 1 to color water from step 3 (add slowly with stirring). Step 5 – Stir and warm to about 50°C until hydrocolloids dissolved (no lumps). Step 6 – Add glycerine and sucralose. Mix until dissolved. Step 7 – Add flavor blend from step 2 and stir until appearance is uniform. Step 8 – Warm glass plate and draw down bar in 55°C oven. Step 9 – Apply film solution to glass plate with draw down bar (0.011 – 0.015 inch; target weight = 0.05g per individual film serving). Step 10 – Dry in oven at 55°C (10 –15 minutes). Do not over dry, or film will become brittle. Step 11 – Cut in rect-

angle shaped individual servings using grid guide. Step 12 - Pack in film container and place in zip-lock bag.

[0030] A descriptive panel was conducted to evaluate the hydrolyzed guar gum formula, Example A, against the Control. Example A showed no difference in cooling levels compared to the Control. However, Example A was quicker to dissolve, not as gummy and had a deeper flavor note as compared to the Control.

[0031] The hydrolyzed guar gum formulation was similar to control as far as curling, but was slightly more brittle. The hydrolyzed guar gum sample, Example A, was a promising alternative backbone formulation for fast dissolving films.

[0032] Additional film formulations, which include hydrolyzed vegetable gums, are presented in Table 2 and Table 3.

Table 2. Examples of Film Formulations with Low Viscosity Hydrolyzed Vegetable Gum

Ingredient	Example B	Example C	Example D	Example E
Water	10.000	10.000	10.000	10.000
Maltodextrin	15.712	17.436	17.681	17.430
Sodium Alginate	14.885	8.469	12.797	1.494
Microcrystalline Cellulose	6.940	6.968	7.067	6.964
Carrageenan	1.819	2.591	3.940	5.976
Hydrolyzed Guar	29.108	32.913	26.588	36.519

Gum				
Glycerin	6.291	6.317	6.405	6.315
Lecithin	0.906	0.910	0.923	0.910
Color	0.258	0.259	0.263	0.259
Menthol	2.987	2.998	3.041	2.998
Flavor	8.501	8.535	8.655	8.532
Sucralose	2.593	2.604	2.640	2.603
Total	100	100	100	100

Table 3. Examples of Film Formulations with Low Viscosity Hydrolyzed Vegetable Gum

Ingredient	Example F	Example G	Example H	Example I
Water	10.000	10.000	10.000	10.000
Maltodextrin	15.597	15.919	16.048	16.048
Sodium Alginate	3.284	11.730	15.134	19.528
Microcrystalline Cellulose	6.889	7.033	7.088	7.088
Carrageenan	0.000	7.038	0.000	8.446
Hydrolyzed Guar Gum	42.851	26.460	29.731	16.891
Glycerin	6.245	6.374	6.426	6.426
Lecithin	0.900	0.918	0.926	0.926
Color	0.256	0.261	0.264	0.264
Menthol	2.965	3.026	3.051	3.051
Flavor	8.439	8.613	8.683	8.683

Sucralose	2.574	2.628	2.649	2.649
Total	100	100	100	100

[0033] The advantages of the preferred embodiments of the present invention provide an economically priced, quickly dissolving edible film with improved mouthfeel, reduced gumminess and no off-flavors.

[0034] It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its intended advantages. It is therefore intended that such changes and modifications be covered by the appended claims.